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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30/04/2002
C(2002) 1832

NOT FOR PUBLICATION

COMMISSION DECISION

of 30/04/2002

relating to the designation of medicinal product "Pseudomonas exotoxin (domains II/III)-Interleukin 13 chimeric protein" as an orphan medicinal product

ONLY THE ENGLISH TEXT IS AUTHENTIC.

COMMISSION DECISION

of 30/04/2002

relating to the designation of medicinal product "Pseudomonas exotoxin (domains II/III)-Interleukin 13 chimeric protein" as an orphan medicinal product

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products¹, and in particular Article 5(8) thereof,

Whereas:

- (1) An application concerning the medicinal product "Pseudomonas exotoxin (domains II/III)-Interleukin 13 chimeric protein" was submitted by the sponsor PPD Global Ltd and validated on 31 January 2002 under Article 5(4) of Regulation (EC) No 141/2000.
- (2) The medicinal product "Pseudomonas exotoxin (domains II/III)-Interleukin 13 chimeric protein" meets the designation criteria of Article 3(1) of the above-mentioned Regulation.
- (3) The favourable opinion of the European Agency for the Evaluation of Medicinal Products, adopted by the Committee for Orphan Medicinal Products on 26 March 2002, was received by the Commission on 28 March 2002,

HAS ADOPTED THIS DECISION:

Article 1

The medicinal product "Pseudomonas exotoxin (domains II/III)-Interleukin 13 chimeric protein" is hereby designated as an orphan medicinal product for the orphan indication: treatment of glioma. It shall be entered in the Community Register of Orphan Medicinal Products under the number EU/3/02/101.

¹ OJ L 18, 22.1.2000, p.1

Article 2

The European Agency for the Evaluation of Medicinal Products shall provide to all interested parties the opinion of the Committee for Orphan Medicinal Products referred to in this Decision.

Article 3

This Decision is addressed to the sponsor PPD Global Ltd, Granta Park, Great Abington, Cambridge, Cambridgeshire CB1 6GQ, United Kingdom.

Done at Brussels, 30/04/2002

For the Commission

Erkki LIIKANEN

Member of the Commission